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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
1635	7

DATE MAILED: 02/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,333	PHILLIPS ET AL.	
	Examiner	Art Unit	
	J. Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 11-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 11-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1, 2 and 11-16 are pending in the application. Claims 3-10 have been canceled as requested in the preliminary amendment dated June 4, 2001. Please note that the preliminary amendment did not request amendment to claims 1 and 2. Therefore the originally filed claims 1 and 2, which are not limited to Mycobacterium phlei, were examined.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,326,357. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are drawn to a composition comprising Mycobacterium phlei cell wall (MCC) wherein the Mycobaterium phlei DNA (M-DNA) is preserved and complexed on the MCC and a pharmaceutically acceptable carrier. Claim 1 of U.S. Patent No. 6,326,357 also claims that the MCC is deprotinated and delipidated, therefore an obvious–type double patenting rejection is appropriate. The species of deprotinated and delipidated MCC with M-DNA preserved and

complexed to the MCC anticipates and therefore renders obvious the Genus of Mycobacterium phlei cell wall (MCC) wherein the Mycobacterium phlei DNA (M-DNA) is preserved and complexed on the MCC.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 16 provides for the use of a composition of MCC for treating or preventing inflammation in an animal, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 16 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claim 15 rejected under 35 U.S.C. 102(a) as being anticipated by Filion et al. (J. Pharm. Pharmacol. Sept. 1998, Vol. 50 (Suppl): p. 39).

Filion et al. teaches a composition comprising Mycobacterium phlei-DNA (M-DNA) preserved and complexed on a Mycobacterium phlei cell wall (MCC) and a pharmaceutically acceptable carrier (see p. 39, second paragraph).

8. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Filion et al. (Blood, Nov. 15, 1997; Vol. 90 No. 10, part 2, Supp. 1; abstract 2959).

Filion et al. teaches a composition comprising Mycobacterium phlei-DNA (M-DNA) preserved and complexed on a Mycobacterium phlei cell wall (MCC) and a pharmaceutically acceptable carrier (see left column, abstract 2959).

9. Claims 1, 2 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Bermudez &Champsi (Infect. Immun. July 1993; Vol. 61, No. 7; p. 3093-3097).

Bermudez & Champsi teaches Mycobacterium avium induces production of IL-10 in mice (see abstract, p. 3093; Table 1, p. 3095). IL-10 is an anti-inflammatory cytokine that has the ability to inhibit macrophage and Type-1 helper T-cell functions (see p. 3093, paragraph traversing col. 1-2; and p. 3096, left col.). Of particular interest, Bermudez & Champsi state, " [T]he antagonistic effect of IL-10 can play an important role in the kinetics of cytokine response following infection with M. avium" and "suppressive cytokines can be advantageous to the bacterium" (see p. 3096, left col.). Therefore, Bermudez & Champsi teach a method of administering to an animal an effective amount of a composition comprising a mycobacterial DNA preserved and complexed on a mycobacterial cell wall and a liquid pharmaceutically acceptable carrier wherein the effective amount is effective to induce the synthesis of cytokine IL-10. This method would effectively treat or prevent inflammation in an animal because the mycobacterium administered is effective to induce the synthesis of anti-inflammatory cytokine IL-10.

10. Claims 1, 2 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Moura & Moriano (Immuno. 1997; Vol 92 No 4; p. 429-436).

Moura & Moriano teaches a method for treating or preventing inflammation in an animal having an inflammation, comprising administering to the animal having inflammation an effective amount of a composition comprising a mycobacterial DNA preserved and complexed on a mycobacterial cell wall and a pharmaceutically acceptable carrier thereby treating or preventing inflammation in the animal (claims 1 and 2); wherein the pharmaceutical carrier is selected for the group of liquid and solid (claim 14) (see p. 429, summary; and p. 430, second column, second paragraph). In particular, Moura & Mariano state (see the summary, p. 429), "These data demonstrated that M. leprea cell wall lipids induce immune suppression in mice..." It is noted that the M. leprea cell wall lipids would inherently comprise the M. leprea DNA, because there is no teaching that the DNA is removed or degraded from the cell wall prior to use.

11. Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Alkemade et al. (U.S. Patent No. 5,759,554).

Alkemade et al. teaches a composition comprising a Mycobacterium phlei-DNA preserved and complexed on a Mycobacterium phlei cell wall and a pharmaceutically acceptable carrier (see col. 2, lin. 53-60; and col. 3, lin. 18-24).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell
February 8, 2002

JEFFREY FREDMAN
PRIMARY EXAMINER